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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/556,941	04/21/2000	Karen Heichman	2318-261	6422

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EXAMINER

NGUYEN, DAVE TRONG

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 05/07/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/556,941

Applicant(s)

HEICHMAN ET AL.

Examiner

Dave Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-45 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *detailed action*.

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Claims 44 and 45 have been added by the response filed Feb. 15, 2002.

Applicant's election of Group I (Claims 1-4, 44-45), and the species of the interaction of IRAP and PTPZ is acknowledged in the response filed Feb. 15, 2002.

However, after a further consideration of the claimed invention and the restriction dated June 19, 2001, the restriction has been vacated by the examiner, particularly since the Group I claims as set forth in the previous restriction do not have unity of the invention and thus contain an enormous number of distinct inventions. Following is the new restriction requirement:

Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-4, 44-45, drawn to an enormous number of protein complexes, readable on class 435, subclass 350.
- II. Claims 5 and 6, drawn to an enormous number of antibodies, classified in Class 424, subclass 134.1
- III. Claims 1-14, drawn to a diagnostic method for identifying a disorder by measuring the presence and/or binding of any of the disclosed protein complexes in an animal, classified in Class 435, subclass 7.1.
- IV. Claims 15-23, drawn to an assaying method for identifying mutation that is useful for diagnostic method by measuring the non-binding of a mutant protein to any of the protein of the disclosed protein complexes, classified in Class 435, subclass 7.1.
- V. Claims 24-28, and 40, drawn to a drug screening assay, readable in class 435, subclass 7.1.
- VI. Claims 29-36, drawn to transgenic animals, readable on class 800, subclasses 13 and 14.

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- VII. Claims 37, drawn to an *in vivo* cell, classified in Class 424, subclass 93.2.
- VIII. Claim 39, drawn to an *in vitro* cell line, classified in Class 435, subclass 325.
- IX. Claim 41-42, drawn to DNA encoding SEQ ID NOS: 4, 6, 8 and 10, classified in Class 536, subclass 23.1.
- X. Claims 43, drawn to polypeptide sequences of SEQ ID NOS: 4, 6, 8 and 10, readable on class 435, subclass 350.

The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods as claimed in Group III, IV and V appear to constitute patentably distinct inventions for the following reasons: Methods cited in inventions III, IV and V are directed to different goal(s) and comprise materially distinct steps that render the methods patentably distinct with respect to their functions and their sites of action.

Groups I, II, VI-X and Groups III-V are patentably distinct because the Groups are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the DNA sequences of Invention IX are not related and/or limited for use any of the claimed methods, the DNA sequences can be used in a gene therapy method or production of recombinant proteins *in vitro*; the antibodies and can be used in DNA vaccination methods. In addition, the polypeptides can be used in protein therapy methods or can be use in any of the respective claimed methods.

Group I-II, and VI-X are distinct from another, because the DNA molecules, the complex of Group I, the polypeptides of Group X, the antibodies of Group II, and the transgenic animals of

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Group IV, the *in vivo* cell of Group VII, the *in vitro* cell of group VIII, respectively, can be employed for a variety of uses, and are not limited to production of respective products as claimed in the restricted Groups. For example, the DNA molecules of Group IX can be employed in hybridization assays, the protein of Group X can be used in production of antibodies, the antibodies of Group II are not even related to that of Groups VI-X and can be used in vaccination, the protein complexes of Invention I are enormous in the breadth and can be used in diagnostic assays, and none of the product claims as claimed in Group I, II, and VII to X are related or limited to the making of the claimed transgenic animal, as indicated above.

Should Group I, II, III, IV, V, VI, VII, VIII, IX or X be elected, the claims of the respective and elected Group are further restricted to a particular complex or interaction as set forth in each respective Table.

In addition, should Groups IX be elected, claims 41 and 42 are further restricted as follows:

Invention directed to DNA encoding SEQ ID NO: 4;

Invention directed to DNA encoding SEQ IDNO: 6;

Invention directed to DNA encoding SEQ ID NO: 8;

Invention directed to DNA encoding SEQ ID NO: 10.

In addition, Should Groups X be elected, claim 43 is further restricted as follows:

Invention directed to DNA encoding SEQ ID NO: 4;

Invention directed to DNA encoding SEQ IDNO: 6;

Invention directed to DNA encoding SEQ ID NO: 8;

Invention directed to DNA encoding SEQ ID NO: 10.

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The inventions wherein each of which is directed to a particular complex as set forth in each Table or to a particular DNA are distinct from one another because of the following reasons:

The inventions are distinct, each from the other because of the following reasons:

As set forth in MPEP 803.02, unity of invention for exists if all species recited in a claim (1) shows a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility. The claims containing a plurality or enormous number of complexes, or the claims containing a plurality of distinct DNA sequences do not have unity of invention because not only a particular protein complex or a particular DNA does not share any substantial structural feature with any other particular protein complex or DNA, respectively, there is no evidence that the protein complexes or the DNA all share any common and specific utility.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their divergent subject matter, fall into different statutory classes of invention, and are separately classified and searched, restriction for examination purposes as indicated is proper, particularly since it would be unduly burdensome for the examiner to search and examine the claimed inventions as presently claimed in the application.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

Any inquiry concerning this communication or earlier communications regarding the formalities should be directed to Patent Analyst Dianiece Jacobs, whose telephone number is **(703) 305-3388**.

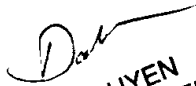
Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Dave Nguyen* whose telephone number is **(703) 305-2024**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Deborah Reynolds*, may be reached at **(703) 305-4051**.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is **(703) 305-7401**.

Any inquiry of a general nature or relating to the status of this application should be directed to the *Group receptionist* whose telephone number is **(703) 308-0196**.

Dave Nguyen
Primary Examiner
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DAVE T. NGUYEN
PRIMARY EXAMINER